

REMARKS

I. Status of the Application

Claims 1, 2, 5-14, 21 and 24-35 are pending in the application. Applicants gratefully acknowledge the Examiner's withdrawal of the rejections of claims 1, 5-14, 21 and 24-35 under 35 U.S.C. §112, second paragraph, as being indefinite; claims 1, 6-8, 10-12, 21, 24-26, 28, 19 and 31-35 under 35 U.S.C. §102(b) as being anticipated by Eitenmuller et al; claims 5, 9, 13, 14 and 27 under 35 U.S.C. §103(a) as being unpatentable over Eitenmuller et al. in view of Pirhonen et al. and Santos et al.; and claim 30 under 35 U.S.C. §103(a) as being unpatentable over Eitenmuller et al. in view of Pirhonen et al. and Santos et al. further in view of Hall et al.

Claims 29-32 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 8 and 26 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1, 2, 5-14, 21, 24-29 and 31-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pirhonen et al., U.S. Patent No. 6,926,903, in view of Santos et al. (1998) *J. Biomed. Mater. Res.* 41:87. Claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pirhonen et al. in view of Santos et al., further in view of Hall et al., U.S. Patent No. 6,730,129. Applicants request entry and consideration of the foregoing remarks, which are intended to place this case in condition for allowance.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Specifically, claim 2 was amended to address formal matters. Claim 29 was amended to remove the term "material." Applicants respectfully submit that the amendments presented herein do not raise new issues requiring further search, and add no new matter.

II. Formal Matters

At page 2, section 6 of the instant Office Action, the Examiner states that the disclosure is objected to for various informalities. The Examiner states that the comma after the word “recent” in paragraph 6, page 1 appears to be misplaced. The Examiner helpfully suggests placing the comma after the word “years.” The Examiner states that second sentence in paragraph 6 appears to require the plural verb “have” as opposed to the singular form “has.” The Examiner also suggests spelling the word “recombinant” to describe the abbreviation “rBMPs” at paragraph 16.

In response, Applicants respectfully submit that the specification has been amended in the manner suggested by the Examiner. Accordingly, Applicants respectfully request that the objection to the specification be reconsidered and withdrawn.

At page 3, sections 10-12 of the instant Office Action, claim 2 is objected to for reciting “of according.” In response, Applicants respectfully submit that claim 2 has been amended to recite “of” and to remove “according to,” thus obviating this objection. Claim 33 is objected to for allegedly misspelling “anorganic.” Applicants respectfully submit that anorganic is correctly spelled. Applicants submit Appendix A, which shows the spelling of anorganic and defines the term as “denoting tissue (e.g., bone) from which the organic material has been removed” (Dorland’s Medical Dictionary, online). Accordingly, Applicants respectfully request that the objection to claims 2 and 33 be reconsidered and withdrawn.

III. Claims 29 and 30-32 Are Definite

At page 3, section 14 of the instant Office Action, claims 29 and 30-32 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out

and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse these rejections.

At section 15, the Examiner objects to the term “glass material.” Without acquiescing to the rejection, Applicants respectfully submit that claim 29 was amended to replace “glass material” with “glass,” rendering the claim definite. The Examiner is also concerned that claims 28, 29 and 32 do not further limit independent claim 21. However, Applicants note that claim 21 recites a carrier of a porous ceramic or glass ceramic or glass. Claim 28 further includes a scaffold with the carrier on the scaffold. Claim 29 recites that the scaffold is made of ceramic, glass ceramic or glass. Claim 32 recites that the scaffold is porous. Accordingly, Applicants respectfully submit that claims 28, 29 and 32 are in proper dependent form.

The examiner is further concerned that the term “glass” in claim 29, metal in claim 30 and polymer in claim 31 lack antecedent basis. However, as discussed above, the referenced materials are described for the first time with respect to the scaffold and are not preceded by the definite article “the.” Accordingly, the terms are proper.

IV. The Specification Provides Adequate Written Description for Claims 8 and 26

At page 4, section 20 of the instant Office Action, claims 8 and 26 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner is of the opinion that the specification does not describe in sufficient detail the claimed polypeptides having bioactivity to place the inventors in possession of the claimed invention at the time of the filing of the application. The Examiner believes that the art is not so predictable that one of skill in the art would be able to identify bioactive polypeptides within the scope of the invention based upon the present disclosure. Applicants respectfully traverse this

rejection. The subject matter of claims 8 and 26 is directed to a bioactive agent selected from a group of agents that includes polypeptides. Applicants respectfully submit that the instant specification identifying polypeptides as bioactive agents within the scope of the present invention meets the written description requirement. Applicants teach that biologically active substances or agents provide an extended therapeutic effect (paragraph [0062]). Applicants teach that these may include polypeptides (paragraph [0062]). Such polypeptides were well known in the art at the time of filing such that Applicants' description of bioactive polypeptides in the present application demonstrates that Applicants were in possession of the invention.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection of claims 8 and 26 under 35 U.S.C. § 112, first paragraph.

V. Claims 1, 2, 5-14, 21, 24-29, 31-35 Are Patentable over Pirhonen in View of Santos

At page 5, section 23 of the instant Office Action, claims 1, 2, 5-14, 21, 24-29 and 31-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pirhonen et al., U.S. Patent No. 6,926,903, in view of Santos et al. (1998) *J. Biomed. Mat. Res.* 41:87. At the outset, Applicants note that the present combination of Pirhonen and Santos were previously applied by the Examiner in the office action dated March 25, 2005 in combination with Eitenmuller as the primary reference. As a result of Applicants' response filed June 20, 2005, the Examiner has withdrawn Eitenmuller as a primary reference, but has maintained the rejection based on Pirhonen and Santos with Pirhonen as the primary reference. Applicants respectfully traverse this rejection.

At the outset, Applicants note that the Pirhonen reference is not a proper reference for an obviousness rejection because it qualifies as prior art only under section 102(e) and the subject

matter of Pirhonen and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. 35 USC 103(c). In support, Applicants note that the face of the Pirhonen patent identifies Inion Ltd. as assignee. Further, the present application has been assigned by the inventors to Inion Ltd. as evidenced by the assignment recorded at reel/frame 014828/0807. Accordingly, Applicants respectfully request that the Examiner withdraw the obviousness rejection based on Pirhonen and Santos.

Furthermore, Applicants rely on the substantive discussion of Pirhonen and Santos as set forth in Applicants' response dated June 20, 2005 and as set forth below. Applicants' substantive views of Pirhonen are being provided even though the Pirhonen reference is not prior art under 103(c).

Pirhonen et al. is directed to resorbable polymer compositions that include a combination of NMP and resorbable polymers or copolymers (column 1, lines 59-61; column 2, lines 56-58). Pirhonen et al. teaches that their *specific combination* of a resorbable *polymer or copolymer* and NMP in a certain ratio unexpectedly provides osteogenic properties (column 2, lines 58-61). Thus, Pirhonen et al. teaches that it is the unique combination of *polymer* and *NMP* that promotes osteogenesis. Pirhonen et al. is not directed to a porous carrier of ceramic or glass ceramic or glass and at least one pyrrolidone, or a porous carrier including calcium phosphate and NMP, as claimed by Applicants, and does not recognize *any* beneficial effects on bone grafting that may be achieved by combining a porous carrier of ceramic/glass and a pyrrolidone. In fact, the Examiner admits that Pirhonen et al. does not disclose a porous carrier comprising ceramic or glass, as claimed by Applicants.

Santos et al. fails to cure the deficiencies of Pirhonen et al. Santos et al. is directed to a bioactive xerogel glass that is used as a carrier for BMP (abstract). Santos et al. teaches that their

xerogel glass can be used to provide a bioactive substrate for bone formation and that the substrate itself provides a hospitable environment for the differentiation of stromal cells into cells that exhibit aspects of the osteoblast phenotype, and teaches that xerogels and BMP act synergistically on rat stromal gel differentiation (page 93, right column, first full paragraph, title). Nowhere does Santos et al. teach the desirability of using a pyrrolidone, let alone producing a porous carrier of ceramic or glass ceramic or glass and at least one pyrrolidone, or a porous carrier including calcium phosphate and NMP, as claimed by Applicants. In fact, Santos et al. is completely silent regarding the use of any pyrrolidone with their xerogels and fails to recognize any beneficial aspects of such a combination. Thus, the combination of references fails to teach or suggest that the claimed combination of a pyrrolidone and a porous carrier of ceramic or glass ceramic or glass has a beneficial effect on bone grafting. Accordingly, one of skill in the art would not arrive at the claimed invention based on the teachings of Pirhonen et al. in view of Santos et al.

The Examiner states that one would have been motivated to produce a composition comprising a porous carrier of glass material as disclosed by Santos et al. and at least one osteogenic pyrrolidone as disclosed by Pirhonen et al., along with a bone morphogenetic protein, because of the need to ensure an effective local concentration of an osteogenic composition during bone formation. The Examiner further states that one of skill in the art would have been motivated to manufacture a porous carrier comprising a glass material/polymer composite to regulate the release parameters of the osteogenic substances, N-methyl-2-pyrrolidone and BMP-2.

Applicants respectfully disagree. Applicants submit that the Examiner is ascribing teachings to Pirhonen et al. that simply are not present. Only Applicants' disclosure provides the

teaching of a combination of a porous carrier of ceramic or glass ceramic or glass and at least one pyrrolidone in a bone grafting material, and the Examiner cannot use hindsight reconstruction to arrive at Applicants' claimed subject matter. Nothing in Pirhonen et al. teaches or suggests the claimed porous carrier of ceramic or glass ceramic or glass and at least one pyrrolidone, or a porous carrier including calcium phosphate and NMP. Further, nothing in Pirhonen et al. would lead the skilled artisan to the claimed invention.

Accordingly, Applicants respectfully request that the rejection of claims 1, 2, 5-14, 21, 24-29 and 31-35 under U.S.C. §103(a) as anticipated by Pirhonen et al. in view of Santos et al. be reconsidered and withdrawn.

VI. Claim 30 is Patentable over Pirhonen in view of Santos further in view of Hall

At page 6, section 24 of the instant Office Action, claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Pirhonen et al., in view of Santos et al., further in view of Hall, U.S. Patent No. 6,730,129. For the reasons discussed above, Pirhonen is not prior art to the present application and, even if it were, fails to teach or suggest the claimed invention whether alone or in combination with Santos. Hall fails to cure the deficiencies of Pirhonen and Santos. Hall is directed to a bone implant having a coating that includes calcium phosphate and a bone-growth stimulating substance (abstract). The Hall reference teaches that a bone-growth-stimulating substance is a TGF- β superfamily member such as a BMP (column 2, lines 43-47). Hall neither teaches nor suggests a porous carrier of ceramic or glass ceramic or glass and at least one pyrrolidone, or a porous carrier including calcium phosphate and NMP, as claimed by Applicants.


Accordingly, Applicants respectfully request that the rejection of claim 30 under U.S.C. §103(a) as anticipated by Pirhonen et al. in view of Santos et al. further in view of Hall be reconsidered and withdrawn.

VII. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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